MODULE ONE:
CORE APPLICATION FORM AND CHECKLIST

State Government Victoria Department of Human Services

BEFORE YOU BEGIN

This Application Form is for use by researchers proposing to conduct a research project involving humans. **All researchers must complete Module 1** and may have to complete other Modules (see checklist at Question 1.6).

Before you start this application, please read the **Module One: Core Application Guidelines** and the National Health & Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* (1999).

Please do not delete the version date in the footer e.g. July 2006.

Office Use Only:

HREC Ref. No._____	Date of Approval: / /
Approval Period:	**From / / To / /**
Approval signature: _____	

SECTION A: PROJECT OVERVIEW

1.1 Application Date: 10 April 07

1.2 Full Project Title

Randomised control trial of advance care planning using the Respecting Patient Choices program in elderly medical patients.

FOR CLINICAL TRIALS ONLY: **Company/Sponsor Protocol Number (if applicable): NA** **Version: Version 1** **Date: 10 April 07**

1.3 Brief Lay Summary of the Project

Briefly describe the project. Refer to the Guidelines for the type of information and level of detail required in your response *(no more than one page) c*

Respecting Patient Choices (RPC) is an advance care planning (ACP) program developed by Austin Health. ACP is a process by which patients, together with their families and health care practitioners consider their values and goals and articulate and document their preferences for future care. The RPC Program trains health care providers, usually nurses and social workers, to become RPC consultants who facilitate discussions with patients and families about advance care planning.

RPC was first implemented at Austin Health in 2002 and has since expanded to a number of ward areas and in some outpatient areas at Austin health. The program has also been implemented at other health services in Victoria, in one lead hospital in each state and in some residential aged care facilities and palliative care services.

Whilst local experience and the literature show level 3 and 4 evidence for the benefit of ACP for improving quality of care, there have been no randomised controlled trials on the efficacy of ACP applied to inpatients and hospital outpatients. The lack of level 1 or 2 evidence impacts significantly on the preparedness of clinicians to accept the value of ACP and of hospital administrators to accept the cost effectiveness of employing staff to facilitate ACP.

Almost 35% of Austin inpatient deaths occur within the first 2 days of admission. ACP is not possible in such patients. However, 60% of deaths occur between 3 and 21 days and almost half of these are in patients who are admitted under general medicine, cardiology and respiratory medicine. Of these deaths 66% occur in those who are 80 years or older.

This study will randomise patients aged 80 or older, who have been admitted under general medicine, cardiology and respiratory medicine for more than 2 days. The control patients will receive their usual care and the intervention patients will, in addition to their usual care, receive an ACP discussion and support to complete ACP documentation, focusing on the appointment of a surrogate decision maker and on identifying the extent of medical treatment that the patient would want in the future. The ACP discussions will be conducted by trained RPC consultants in the patients' wards. The study outcomes will include the frequency of ACP documentation, the types of requests that are made and, if the person subsequently dies, whether their wishes were met. The patient's and family's perception about the quality of care will also be assessed. This information will be obtained from patient files, and by speaking to relatives of deceased patients via telephone. Economic analysis will also be performed. This will be done in consultation with the clinical costing department of Austin health, such that a detailed cost for each patient will be obtained.

This project will be the first prospective randomised control trial looking at these economic outcomes. The information obtained will be published in peer-reviewed journals.

There is no evidence that participating in ACP is associated with any increased risk to patients. Local and overseas experience has found that ACP discussions do not, per se, increase psycho-emotional stress. Indeed the vast majority of patients feed back that the discussion is of great assistance and they report an increased level of satisfaction regarding their hospital care. Our experience also reveals that relatives express an increased level of satisfaction regarding the patient's care and are comfortable about being contacted to provide feedback regarding the patient's care.

1.4 Relationship to Other Projects

Indicate whether the project is

☐ a new stand-alone project

☐ a sub-component of a previously approved project

☒ related to other previously approved projects (e.g. a follow-up study)

If the project is a sub-component of, or in some other way related to, a previously approved project, provide project numbers for the other project(s). Also indicate which HREC(s) approved the other project(s).

H2002/01428 Austin Health,

1.5 Broad Category of Research

Tick the category which best fits the application:

☐ Social Science ☒ Clinical Research

☐ Psychological ☐ Clinical Drug or Device Trial ⇨ CTN ☐ or CTX ☐

☐ Public Health ☐ Other (please specify) ……

1.6 Project Summary

Does the project involve

- Participants? Yes ☒ No ☐
  If yes, please complete section D of Module 1
- Collection, use or disclosure of information? Yes ☒ No ☐
  If yes, please complete section E of Module 1
- Drug or device trial? Yes ☐ No ☒
  If yes, please complete Module 2
- Use of human tissues? Yes ☐ No ☒
  If yes, please complete Module 3
- Human genetic research? Yes ☐ No ☒
  If yes, please complete Module 3
- Use of radiation? Yes ☐ No ☒
  If yes, please complete Module 4

1.7 Multi-Site Projects

Is the project a multi-site project? That is, does the project involve recruitment of participants at more than one site and/or collection of information from more than one organisation?

Yes ☐ No ☒

Does the project have to be reviewed by other HRECs?

Yes ☐ No ☒

Name **all Australian HRECs** to which this project has been or will be submitted. For each HREC, list all Australian sites involved in this project that are covered by the application to that HREC. If the number of sites for a particular HREC is very large (or unknown), such that listing individual sites is not feasible, indicate the number of sites covered by that HREC (*e.g. 50 primary schools or 20 out of 60 child care centres, etc*). Indicate the status of the application to other HRECs.

HREC	**Site**	**Status of application** (*e.g. not yet applied/approved/ rejected/pending*)

SECTION B: RESEARCHERS AND CONTACT INFORMATION

1.8 List all researchers involved in this project

*Copy this table and repeat for each **Principal Researcher**.*

Title and Name	Dr Karen Detering
Appointment	Physician / Clinical Leader
Department	Respiratory & Sleep medicine / RPC program
Institution	Austin health
Mailing address	PO box 5555 Heidelberg 3084
Describe what this researcher will do in the context of this project	Dr Detering will be responsible for the overall running of this project, and ensuring it maintains a high level of ethical and clinical practice. She will be responsible for obtaining consent, and randomising patients, and will oversee the RPC consultants who will be doing the advance care planning. She will be responsible for data collection and analysis.
Include a brief summary of relevant experience for this project	Dr Detering has been a physician at Austin health for over 10 years, and has been actively working as clinical leader in the RPC program since September 2003. She also has a Masters in health ethics. She has a long history of working with patients who are nearing their end of life, and has a vast

	experience in advance care planning.
Phone	9496 3688
Fax	9496 5124
Mobile/pager	0419 874 796
Email	karen.detering@austin.org.au

*Copy this table and repeat for each **Researcher**.*

Title and Name	Dr William Silvester
Appointment	Director / Intensive Care Specialist
Department	RPC Program / Intensive Care Unit
Institution	Austin Health
Mailing address	PO Box 5555 Heidelberg 3084
Describe what this researcher will do in the context of this project	Dr Silvester is the Director of the RPC Program and is responsible for the overall quality and direction of the RPC Program across all RPC sites in Australia. He will share the responsibility for obtaining consent, and randomizing patients, and will oversee the RPC consultants who will be doing the advance care planning. He will participate in data collection and analysis.
Include a brief summary of relevant experience for this project	Overall direction of the RPC Program since the initial pilot project in 2002-2003. Strategic vision and direction of the expansion of RPC across sectors in Australia. Long experience with advance care planning in Australia
Phone	9496 3442
Fax	
Mobile/pager	6150
Email	William.silvester@austin.org.au

1.9 Training

Will any of the researchers require extra training to enable their participation in this project?

Yes ☐ No ☒

If *Yes*, list the researchers, describe the training that is required and who will provide this training.

Researcher	**Training required**	**Who will provide training?**

1.10 Person to whom the HREC may also direct correspondence:

Title and Name	Dr Karen Detering as above

SECTION C: PROJECT DETAILS

1.11 Anticipated duration of project: 6 months to recruit patients, and follow up of patients for 6 months post recruitment (12 months in total)

1.12 Anticipated commencement date at this site: 06/08/2007

1.13 Anticipated completion date at this site: 06/08/2008

1.14 Detailed Project Proposal

If the project is a clinical drug or device trial DO NOT complete question 1.14, but move directly to question 1.15. The detailed p project proposal for clinical drug or device trials is completed in Module 2.

(a) Project Checklist

Major Proposal Components	Page and/or section number in the proposal	Not Applicable
Literature review	Section 1	☐
Rationale for project	Section 2	☐
Hypothesis/research questions	Section 3	☐
Aims	Section 4	☐
Methodology	Section 5	☐
Inclusion/exclusion criteria	Section 6	☐
Randomisation procedures	Section 5	☐
Statistical or other analyses	Section 7	☐

(b) Project Proposal

Every application must be accompanied by a detailed proposal. You may type (or "paste") your detailed proposal directly into the text box below and/or you may attach pre-printed document(s) immediately following this page. Attachments should include brochures/pamphlets, questionnaires or surveys and any other relevant documents. **Ensure that all attachments are page numbered throughout.**

You should consult the Guidelines about the type of information that should be included in the detailed proposal.

Section 1. LITERATURE REVIEW: Version 1: 10 April 2007

A large discrepancy exists between the wishes of dying patients and their actual end-of-life care. Many conflicts arise in medical decision making at the end of life. To address this problem, attempts have been made worldwide to promote the use of advance directives, and advance care planning (ACP). This concept of ACP is not new. With advances in medical technology, and the subsequent ability to prolong life, it has become possible to prolong life in many circumstances, including instances where the resultant life may be of poor quality and not desired by the individual. New technologies are also often expensive, and as health professionals there is a responsibility to ensure the health dollar is utilised appropriately.

ACP is aimed at improving the quality of care an individual receives. This is particularly focused around end of life care. This is based on the ethical concepts of autonomy and informed consent, and the respect of one's dignity. It is an ongoing process that allows patients, in consultation with their families and health care providers, to choose and communicate their future health care wishes. As a consequence of providing optimal and appropriate ACP and end of life care, it is possible there may be some associated cost savings.

ACP has become a major field of interest, especially over the last decade where there has been an increasing number of articles published. The roots of ACP however stem from the political, legal and ethical battles that had their origins in the consumer rights movements of the late 1960's. It was around this time that the "living will' first emerged. During the 1970's many US states developed legislation that enabled patients to document end of life wishes, and legislation allowing for the appoint of substituted decision makers occurred in the 1980's. In 1991 the Patient Self Determination Act (PSDA) was enacted in the USA. In Victoria, the Victorian Medical treatment Act was enacted in 1988. Despite this the majority of doctors in Victoria are unfamiliar with the law and are unaware of the tools available to facilitate advance care planning. Furthermore, according to the Public Advocate of Victoria, the legal instruments of the Medical Treatment Act 1988 have been greatly underutilised.

Despite the moves to legalise the process of advance care planning, there was little evidence for much real change. During the late 1980's and early 1990's there were interventions aimed at improving the uptake of advance care planning. This included the $28 million US study (the SUPPORT study) to look at ways to improve outcomes at the end of life. Despite a large amount of money and effort the end result was poor uptake, with poor quality ACP occurring. Only 21% of patients completed an advance directive, and of those who did the majority only appointed proxies. Very few patients gave specific instructions and, of those provided, many were overturned by their doctors.

After the support study other ACP initiatives have been developed, including the highly successful "Respecting Choices" program from Wisconsin. It is from this project that our program (Respecting Patient Choices) has been adapted. Reasons for success of these programs include the recognition that ACP requires a system wide approach, and that communication is essential to the process. These programs also recognise the need to have skilled advance care planning facilitators with enough time to be available to assist individuals who wish to undergo advance care planning. At Austin health these are known as RPC

consultants. These programs also use education as a means to promote ACP.

The Wisconsin program has succeeded in achieving the following outcomes:
85% of patients who deceased in hospital had completed an advance care plan (increased from 15% pre-program); 96% of plans were available in in-patient medical records (increased from 4% pre-program); and in 98% of deaths the patient's wishes, as stated in the plan were followed. Deceased patients with a plan were 7 fold less likely to die in hospital and 4 fold more likely to have been admitted to a long-term care facility or a hospice prior to death ($p < 0.05$). Deceased patients without a plan were 1.3 times more likely to have been hospitalised in the last 6 months of life and to have cost a median of $2,000 more in hospital services in the last 6 months of life.

Despite the large amount of recent of research which has occurred in the area of advance care planning, to date there have been no randomised controlled trials of ACP in hospital inpatients or outpatients and there has been little research looking at cost justification. As a consequence, we have seen in our implementation of the program at Austin Health and elsewhere that the lack of level 1 or 2 evidence impacts significantly on the preparedness of clinicians to accept the value of ACP and of hospital administrators to accept the cost effectiveness of employing staff to facilitate ACP.

Section 2: RATIONALE OF PROJECT:

Despite the fact that there has been a large amount of interest and research in the field of advance care planning, there is still much to be learnt. In particular there is a lack of level 1 and 2 evidence to support the efficacy of ACP and there has been little research looking at cost benefits of ACP. We expect that if a cost benefit is shown, it will expedite the expansion of ACP to more patients in Austin Health and other health services.

Section 3: PRIMARY HYPOTHESIS

The provision of ACP discussions to appropriate medical inpatients will lead to an improvement in quality of care. Specifically, it will lead to an improvement in the following dimensions of care:

- ACP documentation
- quality of end-of-life care
- compliance with patient wishes
- the patient's and family's perception of quality of care

It is also expected that the costs of managing patients who undergo ACP will be less than for those patients who do not undergo advance care planning.

Section 4: AIMS:

The aims are to demonstrate that ACP leads to an increase in:

- ACP documentation
- quality of end-of-life care
- compliance with patient wishes
- the patient's and family's perception of quality of care

A secondary aim is to investigate the cost effectiveness of ACP in terms of staff costs versus cost savings of avoiding unwanted interventions.

Although ACP is currently available in the Austin it is underutilised. The third aim is that the anticipated results will lead to an increase in utility of ACP in Austin Health patients.

Section 5: METHODOLOGY:

Following informed consent, 300 appropriate medical patients will be randomised (by blocked envelopes) to either standard medical care (control) or to standard medical care plus an ACP discussion by a trained RPC consultant (intervention). The ACP documentation will include the appointment of a future surrogate decision maker (Medical Enduring Power of Attorney) and statement of their wishes. This documentation is currently available at Austin Health in some clinical areas but has been significantly underutilised. If a patient in the control group requests the documentation it will be made available, as is currently the case.

Subsequently the medical records of the participating patients will be inspected for evidence of ACP documentation and, in those patients who have died, evidence that expressed wishes regarding end-of-life care were respected. Three observers who are blinded to the patient's group allocation will undertake the medical record review. If the evidence regarding end-of-life care is not clear from the medical records the patient's Person Responsible (PR) may be interviewed by telephone. At the time of recruitment the researchers will ask the PR whether he/she is happy to be contacted in the future. Their willingness to be contacted in the future will be recorded on the data sheet for future reference by the researchers. The PR will also be given the opportunity to, instead, nominate a third person to be contacted.

The costs to be analysed in each patient will include the bed day and nursing costs (including the different costs for different wards), the costs of all investigations and interventions, the cost of allied health treatment, and the costs associated with any outpatient treatments. This will be undertaken with the advice of the Austin Health Clinical Costing Department and the advice of Prof Hal Swerrison (La Trobe University).

Section 7: Inclusion & Exclusion criteria.

Inclusion criteria are as follows:

Age ≥ 80 years

Speaks English

Competent

Under the care of general medicine, cardiology or respiratory medicine

Has at least one of the following conditions: cardiac failure, ischaemic heart disease, pneumonia, chronic obstructive pulmonary disease, malignancy, severe sepsis or renal failure.

Has been an inpatient for at least 48 hours

Exclusion criteria are as follows:

Patient has previously been introduced to advance care planning or has completed an advance care plan.

Patient has previously been approached to be involved in this research project.

Patient is expected to die within the next 24 hours.

Section 7. STATISTICAL ANALYSIS:

The primary outcome measure is the number of patients whose wishes are known and respected at the end of their lives. There were 900 patients aged 80 or over, admitted to general medicine, cardiology or respiratory medicine in a 6 month period in 2006. Of these 63 died between 3 and 21 days post admission.

There is an expected incidence of documented wishes in the control group of 15% and the anticipated incidence in the intervention group is 65%, resulting in a difference of 50%. Compliance with known wishes is usually > 90%, resulting in an effect size of 0.45. With a 90% power to find a difference between groups, with an acceptable statistical significance of 0.01, the sample size of deaths required in each group will be 20.

To achieve this 600 patients will be recruited over 6 months (3-4 patients per day) of which 300 will be assigned for ACP discussions.

An intention to treat analysis will be performed. Statistical analysis of the effect of ACP will be evaluated using two tailed chi-squared or Fisher's exact test. Data will be presented as mean ± SD. A detailed cost analysis will be performed with the advice of the clinical costing unit at Austin health.

References

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1.15 Reporting

(a) Are there any limitations or restrictions on the publication of results by researchers?

Yes ☐ No ☒

If *Yes*, explain the nature of the limitations or restrictions.

(b) Will a report of the project outcomes (for example, group data) be publicly accessible at the end of the project?

Yes ☒ No ☐

If *Yes*, give details of the type of report and how it will be made available.

If *No*, explain why not.

Following completion of this research the results will be published in national or international peer reviewed journals. It is also expected that data generated by this study will be presented at scientific conferences in the future.

(c) Will a plain English summary of the project outcomes (for example, individual or group data) be made directly available to participants at the end of the project?

Yes ☐ No ☒ N/A ☐

If *Yes*, give details of the type of report and how it will be made available.

If *No*, explain why not.

It is likely that a large number of the participants will have died by the time this research is completed. However a summary of the trial will be available to any participants, or their families, if requested.

1.16 Adverse or Unforeseen Events

What procedures are in place to manage, monitor and report adverse and unforeseen events? Consider adverse events in relation to all aspects of the project, including (where applicable) participants, researchers and management of information.

It is unlikely that such adverse events would occur as this research is considered to represent minimal risk to participants. If an adverse or unforseen event did occur, however, one of the researchers would be available to talk to the affected person and, if required, would organise any follow up assistance necessary, including referral for professional counselling if needed. In our previous research and clinical experience with RPC this has not occurred.

SECTION D: PARTICIPANTS

Researchers should consult the Guidelines under Section D for a definition of "participant" for the purposes of this application.

If the project does NOT involve participants, do NOT complete this section, but go directly to Section E. If you are not completing Section D, you may delete it from your application to avoid unnecessary paper usage.

1.17 Number of participants

(a) Total number of participants in the project (at all sites combined)

600

(b) Break down the number of participants for each site for which this HREC is responsible

Site	No. of participants
Austin health	600

(c) If the project involves more than one project group (e.g. control and experimental groups), how many participants will be in each group?

300 in advance care planning group, 300 in control group

1.18 Participants - Details

(a) What categories of people will be recruited? *(e.g. cancer patients, children, people with learning disabilities, pensioners, etc)*

Austin hospital inpatients, who are competent, English speaking, ≥ 80 years of age with at least one of the following conditions: cardiac failure, ischaemic heart disease, pneumonia, chronic obstructive pulmonary disease, malignancy, severe sepsis or renal failure.

The reason that this trial will not include non-English speaking participants is to avoid confounding factors such as the influence of culture or language. We plan, however, to do further research which would include non-English speaking people, as well as people who lack capacity.

(b) Will Aboriginal and Torres Strait Islander people be targeted for recruitment to this project?

☐ Yes ☒ No

If *No*, are people of Aboriginal and Torres Strait Islander origin likely to be significantly represented in the cohort of participants recruited?

☐ Yes ☒ No

(c) What will be the age range of participants?

≥ 80 years of age

(d) What ethical issues do the criteria for inclusion or exclusion give rise to?

The participants recruited have been selected to make it likely they will be able to participate in advance care planning (speak English and are competent) if they wish to. The age of the patients, and their medical conditions were chosen to optimise the potential benefit of participation in advance care planning. However, many other potentially suitable patients will be excluded, and it is likely many of these people (including younger patients, non English speaking patients, patients with different medical conditions) would also benefit from ACP. Whilst it is not a deliberate move to exclude patients from different cultural backgrounds, it is likely many will be excluded as they are non-English speaking. Finally it is not legally possible to do ACP in non-competent patients, although it is highly likely that many of these people would also benefit significantly from advance care planning.

Whilst ACP will not be promoted in the control group, the option of ACP will be available to any participants in this group if they request it. From our experience the likelihood of such a request is low.

1.19 Recruitment of Participants

(a) Describe the procedure for recruitment of participants. Include information about

- Source of participants
- Exactly how potential participants will be identified
- Exactly how potential participants will be contacted and by whom, including whether the person making initial contact has any relationship to potential participants
- The method(s) by which information is provided to potential participants (*e.g. verbally, information sheet, fliers, posters, etc*)
- The setting in which information is provided (*e.g. over the telephone, in a*

clinic or doctor's surgery, through the mail, etc)

Participants will be recruited from the medical, cardiology and respiratory wards at Austin health. On each weekday, one of the researchers will review the inpatient list and identify any new patients that fulfil the inclusion criteria. Once potential participants are identified, the investigator will be introduced to the patient by a clinician involved in the patient's care. The investigator will then explain the study to the patient and invite them to participate. They will be approached on the ward at Austin Health. They will be provided with some verbal information about the project, and will be given an information sheet to read. If one of the investigators is involved in the clinical care of the patient the other investigator will approach the patient regarding participation.

(b) Will any follow-up procedures be used to improve the rate of participation?

Yes ☐ No ☒

If *Yes*, describe the procedures.

(c) Will any dependent or unequal relationship exist between anyone involved in the recruitment and the potential participants (e.g. counsellor/client, teacher/student, doctor/patient, warder/prisoner, etc)?

Yes ☒ No ☐

If *Yes*:

(i) What is the nature of the dependent or unequal relationship?

Although the participants will be approached by an investigator, who is a doctor at Austin Health, none of the patients will actually be receiving any of their direct medical care by this doctor. One of the investigators does work in the respiratory unit but will have no patient responsibilities on the ward during this project as she will be on sabbatical leave.

(ii) How will ethical issues arising from the unequal relationship be addressed?

The participant will have the nature of the researcher's role explained, and will be reassured that the researchers will not be involved in the delivery of their inpatient medical care. The researcher will also approach the participants in a

calm and sensitive way, and give them every opportunity to decline to be involved in this project.

(d) Will a dual relationship exist between any researcher and participants (e.g. will any of the researchers also be responsible for project, program or administrative oversight within the organisation where it is proposed to recruit participants and carry out the research)?

Yes ☐ No ☒

If *Yes*:

(i) What is the nature of the dual relationship?

(ii) How will ethical issues arising from the dual relationship be addressed?

(e) Will reimbursement, payment or other offers be made to participants?

Yes ☐ No ☒

If *Yes*, provide details.

1.20 Information to Participants

(a) Does the project design involve deliberate deception of participants?

Yes ☐ No ☒

If *Yes*, explain why the real purpose of the research needs to be concealed.

(b) Will information about the project be given to participants in the form of a **written** Participant Information?

Yes ☒ No ☐

If *No*, give reasons.

1.21 Consent

(a) Will any of the participants have the capacity to give voluntary and informed consent? Yes ☒ No ☐

If *Yes*, how will consent be obtained?

☒ Written consent form

☐ Verbal – explain below how consent will be recorded

☐ Implied consent (*e.g. by completing a questionnaire*) – give details

(b) Will any of the participants **not** have the capacity to give voluntary and informed consent? Yes ☐ No ☒

If *Yes*, who will be asked to provide consent *(tick as many as apply)*?

☐ Parent/guardian

☐ Person responsible (as defined by the *Guardianship and Administration Act* 1986)

☐ Procedural authorisation (as defined by the *Guardianship and Administration Act 1986*). ***Please make sure you also answer question 1.21d below***

☐ Other – give details

How will consent be obtained?

☒ Written consent form

☐ Verbal – explain below how consent will be recorded

(c) How will competence to give consent be determined and who will make this determination?

(d) If this research project is likely to involve procedural authorisation (see question 1.21(b) above), provide details of the following: N/A

Competence will be assessed by the researchers who are both physicians. They will determine this in the process of interviewing the potential participants. If there is doubt as to the person's competence they will not be included in this research project.

Justify the potential use of procedural authorisation in the research project - that is, provide details regarding how this research project may satisfy the requirements for procedural authorisation;
Provide details of the steps to be taken to identify and contact a 'person responsible' prior to, and following, the use of procedural authorisation.

ATTACH A COPY OF PARTICIPANT INFORMATION AND CONSENT FORM(S) AT THE END OF MODULE ONE.

1.22 Consequences of Participation

(a) What are the potential or actual harms of participation (if any)?

This research is not expected to be harmful to participants. Whilst it is theoretically possible that participants or their relatives may experience some psychological distress, this risk is likely to be extremely low. Over the time that the RPC program has been operating at Austin health (since 2002), and during previous research with this program there have been no instances of this occurring.

(b) Is there any possibility of inconvenience to participants?

Yes ☒ No ☐

If *Yes*, please describe.

There is a small possibility of some inconvenience to participants who undergo ACP as a small amount of their time will be required. However this can occur at a time that is convenient to the participant. Advance care planning discussions also usually occur over a period time, so the time commitments can be managed appropriately for participants. In the follow-up phase at 3 and 6 months, telephone calls will be made to participants, or (if the participant has died) to their person responsible or other nominated person this may also involve a small amount of inconvenience.

(c) Is there a need for special counselling?

Yes ☐ No ☒

If *Yes*, describe the form of the counselling: how it will be conducted, when and by whom?

(d) Will participants be denied access to other treatments, therapies or services as a result of participation? Yes ☐ No ☒ N/A ☐

Give details.

Patients in the control group will continue to receive medical care in the same way they would have were they not involved in the research. It is anticipated that patients who complete advance care plans will receive care in keeping with their wishes.

(e) Are there any potential benefits to the participants?

It is generally accepted that patients should have access to ACP opportunities. Thus participants who have the opportunity to participate in ACP may gain benefit.

1.23 Other Ethical Issues

Does the project present any other ethical issues with respect to participation? *(e.g. Issues related to illegal activities; indigenous or other special community or cultural groups; risks to third parties, collectivities; etc)*

N/A

SECTION E: COLLECTION/USE/DISCLOSURE OF INFORMATION

Researchers have a legal as well as an ethical obligation to consider privacy issues. The following questions assist both the researcher and the HREC to fulfil their obligations under State and Commonwealth privacy legislation.

You may delete questions or parts of questions that you are not required to answer, in the interests of reducing paper usage.

1.24 Collection of Information Directly from Individuals

(a) Does the project involve collection of information directly from individuals about themselves?

☐ No - **go to Question 1.25**

☒ Yes – answer the following questions:

(b) What type of information will be collected? (*Tick as many as apply*)

☒ personal information

☐ sensitive information

☒ health information

(c) Does the Participant Information and Consent Form explain the following:

The identity of the organisation collecting the information and how to contact it?	Yes☒ No☐
The purposes for which the information is being collected?	Yes☒ No☐
The period for which the records relating to the participant will be kept?	Yes☒ No☐
The steps taken to ensure confidentiality and secure storage of data?	Yes☒ No☐
The types of individuals or organisations to which your organisation usually discloses information of this kind?	Yes☐ No☐
How privacy will be protected in any publication of the information?	Yes☒ No☐
The fact that the individual may access that information?	Yes☒ No☐
Any law that requires the particular information to be collected?	Yes☐ No☒
The consequences (if any) for the individual if all or part of the information is not provided	Yes☐ No☒

If you answered "*No*" to any of these questions, give the reasons why this information has not been included in the Participant Information and Consent Form.

As the majority of information regarding the participant will be collected from hospital records, it was felt that it would not be appropriate to include some of these aspects in the consent and participant information documents. During the usual course of advance care planning some personal and health information may be discussed.

1.25 Do Other Questions in this Section have to be Completed?

(a) Does the project involve the collection, use or disclosure of **identified or potentially identifiable** information from sources other than the individual whose information it is? *(see Module One Guidelines for definitions)*

☐ No – **Go to Question 1.30 and do not answer the remainder of question 1.25, 1.26, 1.27, 1.28 or 1.29**

☒ Yes – **answer the following question**

(b) Does the project involve the collection, use or disclosure of information **without the consent** of the individual whose information it is (or their legal guardian)?

☐ No – **Go to Question 1.30 and do not answer questions 1.26, 1.27, 1.28 or 1.29**

☒ Yes – **answer the following questions**

1.26 Type of Activity Proposed

Are you seeking approval from this HREC for

(a) collection of information from a third party?

☒ Yes – **answer Question 1.27**

☐ No – **skip Question 1.27**

(b) use of information?

☒ Yes – **answer Question 1.28**

☐ No – **skip Question 1.28**

(c) disclosure of information?

☐ Yes – **answer Question 1.29**

☒ No – **skip Question 1.29**

If you have answered 'No' to all three parts of Question 1.26, then go directly to Question 1.30

1.27 Collection of Information from a Third Party

Only answer this question if the project involves the collection of identified (or potentially identifiable) information from a source other than the individual (or their legal guardian) without the consent of the individual or their legal guardian.

(a) From which of the following sources will information be collected? *(Tick as many as apply)*

	Source of Information

☒	A Victorian public health service provider
☐	A Victorian private health service provider
☐	An organisation other than a health service provider
☐	A data set under the auspices of the Victorian DHS
☐	A data set under the auspices of another Victorian government department
☐	A data set from another Victorian source
☐	A Commonwealth agency
☐	An agency from another state
☐	An "organisation" as defined in s95A of the Privacy Act
☐	An individual (such as a carer)
☐	Other

List the categories of individuals or organisations from which information will be collected. If information will be collected from more than one category, indicate clearly what information or records will be collected from each category.

Category	Type of information or records to be collected
Public Hospital records	*medical history*

(b) Have all organisations from which the information is to be collected agreed to provide the information or to allow access to the information?

☐ Yes ☒ No

If *Yes*, provide evidence of this agreement. Provide details of any conditions imposed by the organisation(s) concerning the release of the information.

If *No*, explain how and when the agreement of the disclosing organisation will be obtained.

Files will need to be screened by researchers to determine whether the person fits inclusion criteria prior to the person being invited to participate in this study. The 2 researchers who will access this information are Austin Health employees.

(c) Is any organisation from which the information will be collected seeking separate HREC approval for disclosure of the information? *(See the Module One Guidelines for further explanation of this question. Note: The organisation(s) disclosing the information is not required by law to obtain separate HREC approval to disclose the information. However, some institutions may wish to obtain separate approval for disclosure for their own purposes.)*

☐ Yes – supply a copy of the decision from the other HREC (when available)

☐ No - a copy of any approval from this HREC will have to be forwarded to the disclosing organisation

(d) Does the person who is collecting the information routinely have access to that information?

☒ Yes ☐ No

(e) What information will be collected? (*Tick all boxes that apply*)

	Type of information		**Type of organisation(s) involved**	**Privacy Principle(s)**
☒	Health information	☒	Victorian public sector	HPP 1
		☐	Victorian private sector	HPP 1, NPP 1, NPP 10
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 1, NPP 10
☒	Personal information (other than health information)	☐	Victorian public sector	VIPP 1
		☐	Victorian private sector	NPP 1
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 1
☐	Sensitive information	☐	Victorian public sector	VIPP 10
		☐	Victorian private sector	NPP 10
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 10

(f) Give reasons why information will not be collected in a de-identified form.

As it is necessary to determine participant suitability for the study and then to approach suitable people it is not possible to collect de identified information.

(g) For what reason(s) will consent not be obtained from the individual(s) whose information will be collected?

It is not feasible to obtain consent from all medical, respiratory and cardiology admission for access of medical records to assess whether individuals would be suitable for this research project. It is expected that a large number of potential people need to be screened. It is also likely that a proportion of these people would not be able to give adequate informed consent (due to lack of capacity,

language barriers, close to death).

(h) Give reasons why the proposed collection of information is in the public interest. Note that the public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy.

Giving all patients the option of advance care planning is ethically and legally appropriate. Currently, despite a number of strategies to overcome barriers to implementation of the RPC program, many patients at Austin Health do not get the opportunity to undergo advance care planning. This research project is aimed at establishing level 2 evidence to lead to more patients accessing ACP in the future.

1.28 Use of Information

Only answer this question if the project involves the use of identified (or potentially identifiable) information without the consent of the individual whose information it is (or their legal guardian).

(a) What information will be used? (*Tick all boxes that apply*)

	Type of information		**Type of organisation(s) involved**	**Privacy Principle(s)**
☒	Health information	☒	Victorian public sector	HPP 2
		☐	Victorian private sector	HPP 2, NPP 2
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2
☐	Personal information (other than health information)	☐	Victorian public sector	VIPP 2
		☐	Victorian private sector	NPP 2
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2
☐	Sensitive information	☐	Victorian public sector	VIPP 2
		☐	Victorian private sector	NPP 2
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2

(b) What are the specific purposes for which the information will be used?

Screening to determine if the person meets the inclusion criteria for this study.

(c) Is the purpose for which the information will be used (the secondary purpose) related to the purpose for which the information was **originally** collected (the

primary purpose)?

☐ Yes ☒ No

Give details.

The primary purpose for which the information was collected relates to providing health care for the individual.

(d) Give reasons why information will not be used in a de-identified form. *(If the answer is the same as for Q1.27 (f), write "as above".)*

As above.

(e) For what reason(s) will consent not be obtained from the individual(s) whose information will be used? *(If the answer is the same as for Q1.27 (g), write "as above".)*

As above.

(f) Give reasons why the proposed use of information is in the public interest. Note that the public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy. *(If the answer is the same as for Q1.27 (h), write "as above".)*

As above.

1.29 Disclosure of Information

Only answer this question if the project involves the disclosure of identified (or potentially identifiable) information without the consent of the individual whose information it is (or their legal guardian).

(a) Will identified (or potentially identifiable) information be disclosed by an organisation to the researcher?

☒ No – **Go to question 1.29(b)**

☐ Yes – answer the following question

What information will be disclosed by the organisation(s) to the researcher? (*Tick all boxes that apply*)

	Type of information		**Type of organisation(s) involved**	**Privacy Principle(s)**

☐	Health information	☐	Victorian public sector	HPP 2
		☐	Victorian private sector	HPP 2, NPP 2
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2
☐	Personal information (other than health information)	☐	Victorian public sector	VIPP 2
		☐	Victorian private sector	NPP 2
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2
☐	Sensitive information	☐	Victorian public sector	VIPP 2
		☐	Victorian private sector	NPP 2
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2

List the organisations that will disclose information to the researcher. If more than one organisation is involved, indicate clearly what information or records will be disclosed by each organisation to the researcher.

(b) Will identified (or potentially identifiable) information be disclosed by the researcher to other organisations?

☒ No – **Go to question 1.30**

☐ Yes – answer the following questions

What information will be disclosed by the researcher? (*Tick all boxes that apply*)

	Type of information		**Type of organisation(s) involved**	**Privacy Principle(s)**
☐	Health information	☐	Victorian public sector	HPP 2
		☐	Victorian private sector	HPP 2, NPP 2
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2
☐	Personal information (other than health information)	☐	Victorian public sector	VIPP 2
		☐	Victorian private sector	NPP 2
		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2
☐	Sensitive information	☐	Victorian public sector	VIPP 2
		☐	Victorian private sector	NPP 2

		☐	Commonwealth public sector	IPP 11
		☐	Other	NPP 2

List the organisations to which information will be disclosed. If information will be disclosed to more than one organisation, indicate clearly what information or records will be disclosed in each case.

(c) Give reasons why information will not be disclosed in a de-identified form. *(If the answer is the same as for Q1.27 (f) or Q1.28 (d), write "as above".)*

(d) For what reason(s) will consent not be obtained from the individual(s) whose information will be disclosed? *(If the answer is the same as for Q1.27 (g) or Q1.28 (e), write "as above".)*

(e) Give reasons why the proposed disclosure of information is in the public interest. Note that the public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy. *(If the answer is the same as for Q1.27 (h) or Q1.28 (f), write "as above".)*

1.30 General Issues

(a) How many records will be collected, used or disclosed? Specify the information that will be collected, used or disclosed *(e.g. date of birth, medical history, number of convictions, etc)*

Number of records: All admissions (of at least 48 hours) to general medicine, cardiology and respiratory medicine. **Type of information:** date of birth, medical information, language spoken, evidence of competence, or lack thereof.

(b) Does the project involve the adoption of unique identifiers assigned to individuals by other agencies or organisations?

☐ Yes ☒ No

If *Yes*, give details of how this will be carried out in accordance with relevant Privacy Principles (e.g. HPP 7, VIPP 7 or NPP 7).

(c) Does the project involve trans-border (i.e. interstate or overseas) data flow?

☐ Yes ☒ No

If *Yes*, give details of how this will be carried out in accordance with relevant Privacy Principles (e.g. HPP 9, VIPP 9 or NPP 9).

(d) For what period of time will the information be retained? How will the information be disposed of at the end of this period?

The information obtained without consent will only be retained until the potential participant has been invited to participate in this research project. 1. After consent any information obtained will be retained for at least 7 years from data collection.

(e) Describe the security arrangements for storage of the information. Where will the information be stored? Who will have access to the information?

The information obtained without patient consent will not be stored. Once a patient has consented to the study, any information obtained will be stored securely. The data will all be in electronic format and will be saved to the Austin Health network drive. Access to this network drive is restricted to RPC staff only.

(f) How will the privacy of individuals be respected in any publication arising from this project?

All individuals will be de-identified.

1.31 Other Ethical Issues

Discuss any other ethical issues **relevant to the collection, use or disclosure of information** proposed in this project. Explain how these issues have been addressed.

SECTION F: FINANCIAL AND RELATED ISSUES

1.32 Potential Conflict of Interest

Do any researchers have any financial interests in this research or its outcomes, or any relevant affiliations?

Yes ☐ No ☒

If *Yes*, give details

If you have declared a potential conflict of interest, you should include an appropriate comment on the Participant Information and Consent Form.

1.33 Indirect Costs

Will there be payments over and above the direct costs of this project (e.g. conference and travel, recruitment incentives, equipment)?

Yes ☐ No ☒

If *Yes*, please provide details of payments and justification for them.

1.34 Project Budget

Attach a detailed project budget to this application. N/A

Have you included:

- Salaries with on-costs ☐
- Administration costs ☐
- Research consumables (for example, bed-day costs) ☐
- Participant reimbursement ☐
- Departmental charges (e.g. Pharmacy, Pathology, Radiology) ☐

If a detailed budget is not being provided, give reasons.

The RPC program receives grant funding from the Victorian Government to administer and develop the RPC program at Austin Health. No extra funding is required to do this research.

1.35 Source of Funding

How will this project be funded? List all sources of funds (*e.g. commercial sponsorship, grant, departmental funds etc*).

Source	Amount in $	Status of Funds	
		Application pending	**Funds Available**
Vic Government DHS			Yes

1.36 Funds Coverage

Do the funds presently available or applied for cover all requirements to conduct the project?

Yes ☒ No ☐

If *No*, explain how the shortfall will be made up or dealt with.

1.37 Claims through Medicare

Will any charges be incurred by Medicare as a result of patient screening or participation?

Yes ☐ No ☒ N/A ☐

If *Yes*, has the Health Insurance Commission been notified and have they given permission?

Yes ☐ No ☐

MODULE ONE: CHECKLIST

Please satisfy each of the following before submitting the application. Failure to do so will delay review of the application.

Include a copy of this checklist (completed & signed) with the application.

Full Project Title

Have you answered all relevant questions in Module 1?	☒
Is a staff member from the Institution listed as a co-researcher?	☒
Have you defined all technical terms and abbreviations used?	☒
Have you included all questionnaires or surveys to be used? N/A	☐
Have you completed all financial details in Module 1, Section F?	☒
Have you included a detailed project budget? N/A	☐
Have you declared all potential conflicts of interest? N/A	☐
Have you included any other site-specific modules or documentation specifically required by the Institution(s) at which you intend to conduct your research? N/A	☐
Do the Participant Information and Consent Form(s) show the name of the Institution, with pages numbered & dated in the footer?	☒
Are all relevant modules stapled separately, in order? *Note: Attach attachments for each module at the end of that module*	☒
Are all pages (including attachments) numbered in the footer?	☒
Have you provided an original and the required number of copies?	☒
Have you completed the form "Declaration by Researcher(s)?	☒
Have you completed the form "Certification by Principal Researcher and Head of Department"?	☒
Has a completed "Declaration by Head of Supporting Department" been included for each supporting department (if applicable)?	☒

Name of principal researcher-…….

Signature Date